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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356
42016 7590 01/22/2007 KENSEY NASH CORPORATION 735 PENNSYLVANIA AVENUE EXTON, PA 19341			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/729,146

Applicant(s)

RINGEISEN ET AL.

Examiner

James W. Rogers, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-33, 36-65 and 74-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-33, 36-65 and 74-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendments to the claims filed 11/28/2006 has been entered. Any rejection not addressed below from the previous office action dated 06/23/2006 have been withdrawn.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-33, 38-45, 47-49, 51-53, 61-65, 74-77, 80-81, 84 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574), for the reasons set forth in the office action dated 06/23/2006. Claims 74-77, 80-81, 84 and 87 are newly entered and this new rejection was necessitated by amendment.

Applicants arguments filed 11/28/2006 have been fully considered but are not found persuasive.

Applicants assert that Stone does not disclose nor suggests the claimed invention of newly amended claim 22 which features aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers and with this architecture occurring substantially throughout the structure.

The relevance of this assertion is unclear. Applicants disclosed that the fibrous structure suitable for implantation in a body is produced by compressing a slurry containing biodegradable polymer fibers in a fluid, as disclosed in the previous office

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action dated 06/23/2006, Stone teaches a prosthetic meniscus with one or more types of cross-linked bioabsorbable fibers, which are oriented in phosphate buffered saline solution by compressing with a rotating piston, thus the implant of Stone is produced in the same manner and contains the same components as applicants currently claimed implant, therefore all of the physical limitations for the implant are inherently met.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants further assert that Stone neither discloses nor suggests the invention of newly amended claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked but those located away from the periphery are not cross-linked.

The relevance of this assertion is again unclear. Stone clearly teaches that the GAG crosslinkers employed may be concentrated at different areas including points of high stress, typically the distal regions (14 and 16 in Fig 1) and less concentrated at the central region (12 in Fig 1), the distal region is periphery to the central region, therefore the limitation is met. See col 7 lin 20-35. The examiner considers the fibers within Stone as being aligned see arguments above.

Applicants assert that Stone does not disclose or suggest as described in newly amended claim 39 that the device features fibrous plates in a layered structure, with the layering occurring at both the microscopic as well as macroscopic level, being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation. Applicant lastly asserts that Stone neither discloses nor suggests the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

The argument above also applies to the arguments here, that is since the implant of Stone is produced in the same manner and contains the same components as applicants currently claimed implant all of the physical limitations for the implant are inherently met, thus the limitations of 39 and 42 are met. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Regarding new claims 74-77,80-81,84 and 87, the claims do not add any new limitations that were not addressed from the previous office action or above. Lubricant was defined by the examiner as a substance (usually a liquid) introduced between two moving surfaces to reduce the friction and wear between them, therefore the solution

used in Stone would meet this limitation. The physical characteristics of the implant such as fiber alignment and microscopic laminations are inherently met by Stone, see above arguments.

Claims 22-30, 37-48, 51-65, 74-84 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270), for the reasons set forth in the office action dated 06/23/2006. Claims 76-84 and 87 are newly entered and this new rejection was necessitated by amendment.

Applicants asserts that Li does not disclose nor suggests the claimed invention of newly amended claim 22 which features aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers and with this architecture occurring substantially throughout the structure.

The relevance of this assertion is unclear. Applicants disclosed that the fibrous structure suitable for implantation in a body is produced by compressing a slurry containing biodegradable polymer fibers in a fluid, as disclosed in the previous office action dated 06/23/2006, Li teaches an oriented crosslinked bipolymeric membrane formed by compressing an aqueous solution containing the fibers and orientating the fibers by a rotating mandrel, thus the implant of Li is produced in the same manner and contains the same components as applicants currently claimed implant, therefore all of the physical limitations for the implant are inherently met. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new

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function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants assert that Li does not disclose or suggest as described in newly amended claim 39 that the device features fibrous plates in a layered structure, with the layering occurring at both the microscopic as well as macroscopic level, being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation. Applicant lastly asserts that Li neither discloses nor suggests the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

The argument above also applies to the arguments here, that is since the implant of Li is produced in the same manner and contains the same components as applicants currently claimed implant all of the physical limitations for the implant are inherently met, thus the limitations of 39 and 42 are met. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Regarding new claims 74-84 and 87, the claims do not add any new limitations that were not addressed from the previous office action or above. Lubricant was defined by the examiner as a substance (usually a liquid) introduced between two moving surfaces to reduce the friction and wear between them, therefore the solution used in Li would meet this limitation. The physical characteristics of the implant such as fiber alignment and microscopic laminations are inherently met by Stone, see above arguments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-33, 36-65 and 74-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574) in view of Li et al. (US 2002/0127270) and in



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further view of Haldimann (US 6,428,576 B1), for the reasons set forth in the office action dated 06/23/2006. Claims 74-87 are newly entered and this new rejection was necessitated by amendment.

Applicants assert that Haldimann fails to remedy the deficiencies of Stone and Li and Haldimann does not disclose or suggest the invention of independent claims 31,39 and 42.

The relevance of this assertion is unclear. From the arguments above the examiner believes that Li and Stone do teach applicants claimed invention except for those claims not rejected above. Haldimann was only used for its disclosure within that implantable bio-polymers were already known at the time of the invention to contain plasticizers and particulates. Since Haldimann was used in a 103(a) rejection as a secondary reference it does not have to disclose all of the limitations of applicants claimed invention, if it would have been obvious at the time of the invention to combine the references used in the rejection. The examiner believes it would have been obvious to one of ordinary skill in the art to combine all of the above references because they are all related to the same field of endeavor, implantable bio-polymers.

Regarding claim 36, since applicants claimed implant is comprised of the same components and is made in the same way as the Li and Stone references, the implants within Li and Stone would obviously be capable of swelling upon implantation and exposure to a body fluid, the intended use that the implant would function as a hemostatic plug was given no patentable weight by the examiner. Once again the case law of In re Best would appear to apply because it appears that applicants are claiming

a new use of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

### **Conclusion**

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

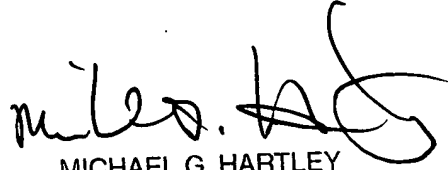
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER